K090192

Interlectric Corporation

1401 Lexington Ave.
Warren, PA. 16365

Ph. 814-723-6061
fax 814-723-6069

510(k) Summary as required by section 807.92(c)

Submitter Information

Interlectric Corporation
1401 Lexington Ave.
Warren, PA. 16365
814-723-6061
fax 814-723-1074
Contact: Ken C Frazier

APR 2 4 2009

Reason for Submission: New Device

Summary prepared on December 28, 2008

Device Name

Trade Name:	Bili Blue F20T12/BBY and F40T12/BBY
Common Name:	2-foot and 4-foot T12 Blue fluorescent lamps
Classification Name:	Unit, Neonatal Phototherapy (21 CFR 880.5700, product code LBI)

Predicate Device

F40 and F20; Philips Special Blue; Philips Lighting Co., Division of Philips Electronics

Product Description

The Interlectric Bili Blue F20T12/BBY and F40T12/BBY devices are standard 2-foot and 4-foot T-12 fluorescent lamps that contain a phosphor composition that emits blue light energy in the range between 400 – 500 nanometers and produces no energy in the ultraviolet region of the spectrum.

K080192

Indications for Use

Interlectric Bili Blue F20T12/BBY and F40T12/BBY lamps are used in the treatment of Hyperbilirubinemia in newborn infants. The lamps are placed in commercially available luminaries that will concentrate the blue light energy.

Technological Characteristics

Phototherapy for treating Hyperbilirubinemia in newborn infants is a well-established clinical practice. Exposure to light from blue fluorescent lamps for such treatment was adopted in the United States back in the 1970's. Comparison testing between the New Device and the Predicate Device demonstrates that the New Device lamps are substantially equivalent to the Predicate Device lamps with respect to:

-Intended Use (Treatment of Hyperbilirubinemia)

- Spectral output in the effective range (400 – 500 nanometers)

- Ultraviolet Radiation Safety

-Conformity to ANSI Specifications for Dimensional and Electrical Characteristics for fluorescent lamps (ANSI C78.2-1978 and ANSI C78.1-1991)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ken C. Frazier
Engineering Manager
Interlectric Corporation
1401 Lexington Avenue
Warren, Pennsylvania 16365

APR 24 2009

Re: K090192
Trade/Device Name: 2-Foot and 4-Foot T12 Blue Flourescent Lamps
Trade Name: "Bili Blue F20T12/BBY and F40T12/BBY"
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: December 28, 2008
Received: January 27, 2009

Dear Mr. Frazier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.1

Indications for Use

510(k) Number (if known): _____

Device Name: 2-foot and 4-foot T12 Blue fluorescent lamps
Trade Name: "Bili Blue F20T12/BBY and F40T12/BBY"

Indications for Use:

Interlectric Bili Blue F20T12/BBY and F40T12/BBY lamps are used in the treatment of Hyperbilirubinemia in newborn infants. The lamps are placed in commercially available luminaries that will concentrate the blue light energy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090193